DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

JUL 27 2000

8030 '00 AUG -1 A10:00

Hugh L. Moore
Keith D. Parr
Terrence P. Canade
Deanne M. Mazzochi
Lord, Bissell & Brook
115 South LaSalle Street
Chicago, Illinois 60603

Re: Docket No. 00P-0499/CP1

Dear Mr. Moore, Mr. Parr, Mr. Canade, and Ms. Mazzochi:

I am writing to inform you that the Food and Drug Administration (FDA) has not yet resolved the issues raised in your citizen petition received by the Dockets Management Branch on February 4, 2000. You request that the Agency remove two patents, U.S. Patent Nos. 5,900,423 and 5,872,132, from the Orange Book (*Approved Drug Products with Therapeutic Equivalence Evaluations)*. You also request that we refuse to permit those or future patents claiming SmithKline Beecham Pharmaceuticals' paroxetine hydrochloride to interfere with or delay our review and approval of the abbreviated new drug application (ANDA) filed by the TorPharm Division of Apotex, Inc. (ANDA No. 075-356) for the drug product.

The Agency is still evaluating the request made in your petition, and will respond once this process is completed. This interim response is provided in accordance with FDA regulations on citizen petitions (21 CFR 10.30(e)(2)). We will respond to your petition as soon as we have reached a decision on your request, which we expect will be in the very near future.

Sincerely yours,

Janet Woodcock, M.D.
Director
Center for Drug Evaluation and Research

00P-0499

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